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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,972	05/11/2001	Barry Ross	017227/0171	7954

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EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/786,972

Applicant(s)

ROSS, BARRY

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01/12/04 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Examiner acknowledges receipt of amendment and corrected drawing filed 01/24/04.

Claims 1-11 are pending.

Drawings

The Examiner accepts the new formal drawings filed in response to the objection raised in the last office action.

Claim Rejections - 35 USC § 102

1. Claims 1-11 remain rejected under 35 U.S.C. 102(b) as being anticipated by Matthews et al. (WO 95/34595).

Arguments

Applicants argue that a) instant claim 1 recites a "method for inhibiting the activity of a toxic material or substance ... selected from the group consisting of toxins and toxic peptides of biological origin, and toxins and toxic peptides released during bacterial, protozoal, fungal or viral infection;" b) the evidence of record does not show that a person of ordinary skill in the art would reasonably interpret "toxic material or substance" to encompass a virus; c) Matthews discloses compounds and compositions for treating infections caused by viruses such as HIV and that a person of ordinary skill in the art would not equate virus with toxin and vice versa; d) toxic materials or substances cannot embrace the actual viruses and that the specification at page 9, lines 4-10, explicitly teaches that "toxic materials or substances' ... refer in particular to toxins of biological...origin,...and toxic peptides or other materials or substances released during bacterial infection..., or during protozoal, fungal or viral infection." Nothing in that passage

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suggests that the phrase "toxic materials and substances" comprehends viruses and that figure 1 properly interpreted in the context of Example 40, clearly demonstrates in vitro inhibition of the toxic Vpr P3 fraction that is produced by HIV, and not inhibition of HIV itself.

Response to Arguments

2. Applicant's arguments filed 01/12/04 have been fully considered but they are not persuasive.

Regarding argument or presentation a), Examiner agrees with applicants that amended claim 1 specifically defines toxic material or substance as toxins and toxic peptides of biological origin, and toxins and toxic peptides released during bacterial, protozoal, fungal or viral infection; and in presentation d), applicants cite the section of applicants' specification, page 9, lines 4-10, which discloses toxic materials or substances as "toxic peptides or other materials or substances released during bacterial infection (such as bacterial endotoxins and exotoxins), or during protozoal, fungal or viral infection." It is respectfully submitted that HIV is a virus that infects a subject and during that infection releases substances that afflict the infected subject and in this regard HIV infection releases substances that meet the limitation that toxin is a substance released during viral infection. Therefore, regarding presentation b), because applicant's presentations a) and d) which state that viral infection produces substances or materials that are toxins; and because Matthews discloses treating HIV infection with cationic dendrimers, it naturally flows that a person of ordinary skill in the art would interpret HIV infection as producing substances that are defined by applicant as toxin and therefore the prior art meets the

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limitation of inhibiting the activity of a toxic material or substance, which is a form of treating by holding in check those viral-produced substances from doing harm to the infected/afflicted subject. At the time the examiner held the position that "toxic material or substance" encompassed a virus, cancelled claim 15 recited virus as a biological organism and lines 5-8 of applicant's specification define "toxic materials or substances" as "toxins of biological (animal, plant, microbial or viral) origin." If the correct interpretation of the cited section is that toxins are of biological origin and are produced by animal, plant, microbial or virus, then a toxin cannot be the virus itself but the substance produced by the viral infection continues to be toxin as per applicants' definition and Matthews meets that limitation. Thus regarding presentation c), while the person of ordinary skill in the art after the cancellation of claim 15 and review of applicant's specification would not equate toxins with virus and vice versa, the person of ordinary skill in the art would reasonably interpret that the dendrimer of Matthews is employed to treat or inhibit the substances produced by the viral infection. Regarding example 40 in the application, the title reads "Inhibition of HIV (AIDS) Toxin" and Vpr is defined in line 1 as "an Human Immunodeficiency virus (HIV-1) accessory gene product." Therefore, in conjunction with Figure 1, the interpretation is not in comprehending viruses as toxins but rather viruses produce toxins as stated by applicant in the arguments. Reference to Figure 1 in the last office action is related to inhibition of substance produced by HIV.

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Double Patenting

3. Claims 1-12 and 15 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36, 38 and 39 of U.S. Patent No. 6,190,650.

Arguments

Applicants traverse the double patenting rejection on the grounds of the argument presented for the rejection under 35 USC 102(b) and that treatment of infections that are caused by toxins or toxic material should not be construed as treating viral infections.

Response to Arguments

4. Applicants' arguments filed 01/12/04 have been fully considered but they are not persuasive.

Specifically, claim 38 of the issued patent administers the composition of the issued claim 1 to treat viral infection as clearly stated in issued claim 39 where anti-viral treatment is treatment of infection by a virus. Inhibiting the activity of a toxic material, which is a material produced by a viral infection (last 3 lines of instant claim 1) is an aspect of treating a viral infection. Issued claims 2-36 are dependent on issued claim 1 and said claims are encompassed in instant claims 2-11. Thus the rejection under the judicially created doctrine of obviousness-type double patenting is proper and is maintained.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference

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claims because the examined claim is either anticipated by or would have been obvious over the reference claims. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Response to Amendment

There is no indication in claim 7 that claim 7 is currently amended. Specifically, --- dendrimer--- may be inserted after "said" and before "is" in line 1 of claim 7. There is also no indication in claim 11 that claim 11 is currently amended. Correction is respectfully requested.

No claim is allowed.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 242-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Blessing Fubara
Patent Examiner
Tech. Center